Kansas Medical Assistance

DRUG UTILIZATION REVIEW BOARD

Meeting Minutes, Open Session

November 12, 2003

DRUG UTILIZATION REVIEW BOARD Meeting Minutes, Open Session Memorial Hall, Auditorium Topeka, Kansas November 12, 2003	**Members Present:** Michael Burke, M.D., Ph.D., Chair, R. Kevin Bryant, M.D., CMD, Dennis Grauer Ph.D., John Lowdermilk, R.Ph., Barry Sarvis, R.Ph., Brenda Schewe, M.D., Kevin Waite, Pharm.D., John Whitehead, D.O. **SRS Staff Present:** Nialson Lee, B.S.N, M.H.A., Mary Obley, R.Ph., Vicki Schmidt, R.Ph., DUR Program Director, Erica Miller **EDS Staff Present:** Karen Kluczykowski, R.Ph.	**Representatives:** Judy Bowlby (Schering-Plough), Gary Pedersen (Bayer), Barry Adams (Upjohn), Mike Huffles (Ks Governmental Consulting), James V. Rider, D.O. (Geriatrics), Debbie King (Amgen), Jim Baumann, R. Ph (Pfizer), Barbara Belcher (Merck), Bruce Steinberg (Aventis), Rick Shepard (MedImmune), Candie Phipps (Boehringer Ingelheim), Myrle Myers (Johnson & Johnson), Laura Wyatt (Aventis), Dan Robson (Pfizer), Mike Moratz (Merck & Co, Inc.), Arnie Bazemore (Sepracor), Nancy Zogleman (Pfizer), Brett Spencer (Purdue Pharma), James Lieurance (Takeda), Kathleen Carmody(Lilly), Craig Boon (Heritage Information Systems, Inc.), Margaret Cavanaugh (Heritage Information Systems, Inc.), Conrad Duncan, M.D. (University of Kansas Medical Center), Hank Hershey (Aventis Pharma), Loren Jordan (MedImmune), Stephanie Miller (Amgen), Jim Goddard (Shire), Charles Duhn (Amgen), Diana Morasch (AstraZeneca), Susan Zalenski (Sanofi-Synthelabo), Randy McGinley (Berlex), Mike Ketcher (Novartis), Kate Kulesher (Wyeth), Chris Hunt (King), Joe Wayman (Biovail), David Delay (Biovail), Tom Rickman (Aventis), Carol Curtis (AstraZeneca), Ron Godsey (TAP) Randy Goldstein, M.D. (Pediatrics, Lansing, KS)

TOPIC	DISCUSSION	DECISION/ACTION
I. Call to Order	• Dr. Michael Burke, Chair, called the Open Meeting of the Drug Utilization Review Board to order at 9:35a.m.	
II. Introduction of New Drug Utilization Review Members	• Dr. Burke introduced the new Administrative Assistant, Erica Miller and the new Board Member, Dennis Grauer, Ph.D.	
III. Review and Approval of September 10, 2003, Meeting Minutes	• There were no additions or corrections to the September 2003 meeting minutes.	• A motion to approve the minutes as written was made by Dr. Schewe and seconded by Dr. Whitehead. The motion carried unanimously by roll call.
IV. Old Business **A. Review Prior Authorization Criteria for Anticholinergic Urinary Incontinence Drugs**	• Dr. Burke stated that Anticholinergics were reviewed at the last meeting and the Board requested more information. • Vicki explained that the criteria was modified. If the patient is 70 or older they are automatically exempt from the PA process. • Dr. Burke stated that at the September meeting their concern was the availability for the elderly. Over half the beneficiaries utilizing these drugs are 70 years of age and above. Oxybutynin would be the Preferred Drug if the patient does not meet the age requirements.	
Public Comment	• Dr. James Ryder (Valley Falls, KS) stated that he does not know how the age of 70 was chosen. He stated that dementia often starts before 70. He urged the DUR Board to do away with the age 70 and let the physicians use whatever drug they think is appropriate. • Dr. Conrad Duncan (University of Kansas) stated that the most commonly complained about side effects of Oxybutinin are dry mouth and constipation.	
DUR Board Discussion	• Dr. Burke pointed out that the Preferred Drug List	

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DUR Board Recommendation	(PDL) Committee determined that there is no significant clinical difference. In a 2003 Oregon based analysis there were no clinical differences found. • Dr. Whitehead stated that he would be in favor of the criteria if we lowered the age to 50. • Dr. Bryant agreed with Dr. Whitehead. • Dr. Burke stated that if we lowered the age to 50, 85% of the users would not need a Prior Authorization. • Dr. Schewe stated that the age should be dropped or the PA should be eliminated. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Whitehead and seconded by Mr. Lowdermilk to decline the SRS recommendation for generic Oxybutynin 5mg tablets and generic Oxybutynin syrup to be the preferred Anticholinergic Urinary Incontinence Drugs. The motion carried unanimously by roll call.
B. Anti-Emetics/Diagnosis Codes	• Dr. Burke pointed out that we currently do not require a Prior Authorization for Anti-Emetic medication. The Board was interested in the diagnosis because of the high cost. • Mary stated that the PDL reviewed Anti-Emetics and found clinical equivalence. After review, SRS determined that Zofran® would be the preferred agent. • Vicki stated that this is information that the DUR Board requested in July. It was unexpected that so many of the diagnosis would be for pregnancy and nausea. • Dr. Burke recommended education for the providers.	

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Anti-Emetics - Continued	• Dr. Waite points out that people should not be on Anti-Emetics for long periods of time. If it is not working they need to try different methods. These drugs are for one or two doses, not long-term use. There are better products for chronic conditions. • Dr. Schewe asked if we should require Prior Authorization for Anti-Emetics, with cancer and post-op receiving an automatic Prior Authorization. • Vicki suggested that DUR do education through Heritage and then have the DUR Board review again later. • Mary stated that Zofran® will be the preferred Anti-Emetic and all the rest will need Prior Authorization.	
C. Review Ambien/Sonata Paid Claims and Quantities Dispensed **Public Comment** **DUR Board Discussion**	• Dr. Burke points out that this is in response to a request made by the Board at the September meeting. Ambien and Sonata are being prescribed for longer than the FDA recommended time period of two weeks. • Chris Hunt (King Pharmaceuticals) spoke about Sonata. • Dr. Schewe stated that we should look at limiting the quantity. • Karen stated that EDS could restrict quantities. • Dr. Bryant stated that there are few patients taking Ambien or Sonata long-term in the nursing homes. Nursing homes try to avoid leaving patients on Ambien or Sonata for long periods of time. • Dr. Burke stated many third party insurance companies limit quantities.	

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Ambien/Sonata-Continued	• Dr. Schewe stated that other insurances follow what the FDA says. FDA states that Ambien/Sonata should not be taken for longer than 14 days, so after the 14 days most insurance will not cover it. • Dr. Burke stated that they will table Ambien/Sonata for now and would like a template for Prior Authorization, including quantity limitation.	
V. New Business **A. FluMist®** **Discussion of Prior Authorization Criteria** **Public Comment** **DUR Board Recommendation**	 • Dr. Burke inquired, if providers or beneficiaries are requesting FluMist®. • Karen replied that no one has requested it because there is no CPT code so it is not currently covered. • No public comment. • With no further Board discussion, a motion was placed before the Board.	 • A motion was made by Dr. Waite and seconded by Dr. Bryant to accept the SRS recommendation for FluMist®. The motion carried unanimously by roll call.
B. Synagis® **Discussion of Prior Authorization Criteria** **Public Comment** **DUR Board Recommendation**	 • Dr. Burke stated that Synagis® requires Prior Authorization. This is a modification due to the latest indication by the FDA. • No public comment. • With no further Board discussion, a motion was placed before the Board.	 • A motion was made by Dr. Whitehead and seconded by DR. Schewe to accept the SRS recommendation for Synagis®. The motion carried unanimously by roll call.

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C. Etanercept (Enbrel®)		
Discussion of Prior Authorization Criteria	• Dr. Burke stated that the Etanercept (Enbrel®) Prior Authorization was modified due to a new FDA indication.	
Public Comment	• Charles Dunn (Amgen) stated that the diagnosis of active ankylosing spondylitis does not require an inadequate response to DMARD's.	
DUR Board Discussion	• Dr. Burke suggested adding an exception to the criteria to exclude an inadequate response to DMARD's with the diagnosis of active ankylosing spondylitis. • Mr. Lowdermilk asked why we need a Prior Authorization for Etanercept (Enbrel®). • Vicki replied that we want to make sure it is used correctly.	
DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Waite to accept the SRS recommendation with the addition of, with exception of active Ankylosing Spondylitis, which requires two or more NSAIDs previously, added to #2 on the Prior Authorization Criteria. The motion carried unanimously by roll call.
D. Zyrtec®		
Discussion of Prior Authorization Criteria	• Dr. Burke stated that SRS selected Zyrtec® as the preferred agent for Non or Less-Sedating Antihistamines Group. • Mary pointed out that the Non or Less-Sedating Antihistamines group were all found to be clinically equivalent by the PDL committee. • Dr. Burke stated that Loratadine is now available as a generic so there is considerable cost	

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Zyrtec - Continued **Public Comment** **DUR Board Discussion** **DUR Board Recommendation**	savings with the generic Loratadine. • Dr. Randy Goldstein (Pediatrics, Lansing, KS) informed the Board that he prescribes Non or Less-Sedating Antihistamines to children starting at age 6 months. He does not believe they are all clinically equivalent and he states that there have been studies done showing the differences. • Laura Wyatt (Aventis) stated that there are 3 other companies that make Non or Less-Sedating Antihistamines for children that cannot swallow tablets. • Bruce Steinberg (Aventis) points out the Loratadine has a syrup and there will be an over the counter syrup soon. • Dr. Burke stated that the Preferred Drug List Committee makes recommendations to SRS and the DUR Board. The DUR Board then reviews the information and Prior Authorization criteria for the non-preferred agents. SRS then selects the preferred drug(s). • Dr. Schewe stated that she does not believe all Non or Less-Sedating Antihistamines are clinically equivalent. • Mary stated that this preferred drug was chosen due to cost and the fact that it is available as a syrup for children. • Dr. Burke noted the proposed Prior Authorization criteria excludes all children under age 12, regardless of formulation. • With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Bryant and seconded by Dr. Schewe to accept the SRS recommendation with the following additions. Generic Loratidine, generic

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Zyrtec - Continued		Loratidine/Pseudoephedrine, and Zyrtec® syrup(12 & under only) added to be the preferred Non or Less-Sedating Antihistimines. Prior Authorization would be needed for Zyrtec®, ZyrtecD®, Allegra®, AllegraD®, Claritin®, ClaritinD 12hr®, ClaritinD 24hr®, and Clarinex®. A roll call was taken Mr. Sarvis, Mr. Lowdermilk, Dr. Waite, and Dr. Grauer voted no while everyone else voted yes. The motion did not pass.
DUR Board Discussion	• Mr. Sarvis stated that if patients are successfully being treated on another Non or Less-Sedating Antihistamine, he sees no reason to switch. • Mr. Lowdermilk questioned if a patient is 14 years of age and needs the syrup, would they be able to get it? • Mary answered the doctor would need to fill out the Prior Authorization stating the patient cannot swallow tablets under the absence of appropriate formulation section and the patient would be able to get the syrup. • Dr. Burke suggested not including Zyrtec® syrup in the preferred list and requiring Prior Authorization. • Dr. Schewe stated that all of the Non or Less-Sedating Antihistamines need to be listed. Included in the list should be notations of drugs available with certain ages.	
DUR Board Recommendation	• With no further Board discussion, a motion was placed before the Board.	• A motion was made by Dr. Schewe and seconded by Dr. Bryant to accept the SRS recommendation with the following additions. Generic Loratadine Tabs and Syrups, generic Loratidine/Pseudoephedrine (KBH Only), and Cetirizine® Syrup (12 and Under Only) added

TOPIC	DISCUSSION	DECISION/ACTION
Zyrtec - Continued		to the preferred Non or Less-Sedating Antihistimines, and Prior Authorization required for Zyrtec®, ZyrtecD®, Allegra®, AllegraD®, Claritin®, ClaritinD 12hrs®, ClaritinD 24hr®, and Clarinex®. Then a note was added: ZyrtecD®, AllegraD®, ClaritinD 12hr®, ClaritinD 24hr® are covered for Kan-Be-Healthy beneficiaries (KBH) ONLY through Prior Authorization. The motion carried unanimously by roll call.
VI. Meeting Adjournment	• There being no further discussion, a motion to adjourn was placed before the Board.	• A motion was made by Dr. Whiteside and seconded by Dr. Bryant to adjourn the meeting. The motion carried unanimously. The open meeting was adjourned at 11:40 a.m.